

HEALTH CARE BENEFITS FOR CHILDREN OF VIETNAM VETERANS**CHAPTER: 2****SECTION: 3****TITLE: PHARMACY SERVICES, SUPPLIES, AND OVER-THE-COUNTER
ITEMS**

AUTHORITY: 38 CFR 17.900 and 17.901

I. DEFINITIONS

A. Legend drugs are drugs that require a prescription by law.

B. Investigational new drugs (IND) are medications for which a new drug application has been filed with the Food and Drug Administration (FDA). An investigational drug may be a new chemical compound that has not been released by the FDA for general use. It may also be an approved drug that may be used for an unapproved or approved use in a controlled, randomized, or blended clinical trial. Investigational drugs usually are not available through commercial channels.

C. Over-the-counter items can include pharmaceuticals, continence-related supplies (catheters, disposable pads, and diapers), and other supplies that are medically appropriate and necessary for a covered condition. Items are normally used for daily care of patients and are usually obtained from private suppliers such as drug stores, discount stores, or grocery stores.

D. Unlabeled or off-labeled drugs or medical devices are used for a condition, diagnosis or indication for which the FDA has not approved its use.

II. POLICY

Drugs and medications, including unlabeled or off-label use, are covered when all of the following conditions are met:

1. The drug is medically necessary for the treatment of the covered condition(s).
2. The drug is administered according to accepted standards of medical practice.
3. The drug is approved by the FDA for commercial marketing.
4. The drug is prescribed and dispensed in accordance with applicable state law and licensing requirements.

III. POLICY CONSIDERATIONS

- A. Parenteral or enteral feeding is a benefit if related to the covered condition.
- B. Expendable supply items such as catheters, colostomy or ileostomy sets and supplies, plastic or rubber gloves, skin preparations and powders for orthotic and prosthetic appliance wearers, urinals, leg or canister-type urinary drainage supplies, and incontinence supplies are allowable benefits for the covered condition.
- C. Approval for unlabeled or off-label use requires medical review for medical necessity.
- D. If the off-label or unlabeled use of the drug is not in accordance with nationally accepted standards of practice in the medical community and safety and effectiveness is questionable, then coverage for the drug will be denied.
- E. Oxygen therapy and supplies are covered when medically necessary for the treatment of the covered condition.

IV. EXCLUSIONS

- A. Drugs not approved by the FDA for commercial marketing.
- B. Placebo injections and drugs.
- C. Experimental/investigational (unproven) drugs.
- D. Items such as bed linens, specialty garments, and clothing.
- E. Drugs prescribed or furnished by a member of the patient's immediate family.

END OF POLICY